JUDGE CASTEL

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

TAKEDA PHARMACEUTICAL CO., LTD., TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, AND TAKEDA PHARMACEUTICALS AMERICA, INC., Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD., AND DR. REDDY'S LABORATORIES, INC., Defendants.	CASE NO. **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals LLC, and Takeda Pharmaceuticals America, Inc. (collectively, "Plaintiffs"), state the following as their Complaint against Defendant Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Dr. Reddy's Laboratories" or "Defendants"):

I.

THE PARTIES

1. Plaintiff Takeda Pharmaceutical Company Limited ("TPC") is a Japanese corporation with its principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, Japan. TPC's business includes the research, development, and marketing of pharmaceutical products.

2. TPC is the owner of record and assignee of U.S. Patent No. 6,664,276 (the "'276 Patent") and U.S. Patent No. 7,790,755 (the "'755 Patent") (collectively, the "Asserted Patents").

3. Plaintiff Takeda Pharmaceuticals North America, Inc. ("TPNA"), is a Delaware corporation with its principal place of business at One Takeda Parkway, Deerfield, IL 60015. TPNA's business includes the research, development, and marketing of pharmaceutical products. TPNA is the registered holder of approved New Drug Application No. 22-287. In addition, TPNA has the exclusive right to import dexlansoprazole delayed release capsules into the United States and sell those capsules to Takeda Pharmaceuticals LLC.

4. Plaintiff Takeda Pharmaceuticals LLC ("Takeda LLC") is a Delaware limited liability company, having a principal place of business at One Takeda Parkway, Deerfield, IL 60015. Takeda LLC's business includes the purchase and sale of pharmaceutical products. Takeda LLC is an exclusive licensee of the Asserted Patents.

5. Plaintiff Takeda Pharmaceuticals America, Inc. ("TPA"), is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, IL 60015. TPA's business includes the purchase, sale, and marketing of pharmaceutical products. TPA

has the exclusive right to purchase dexlansoprazole delayed release capsules from Takeda LLC and sell those capsules to the public in the United States.

6. Plaintiffs are informed and believe, and thereupon allege, that Defendant Dr. Reddy's Laboratories, Ltd. ("DRLL") is an Indian corporation with its registered office at 7-1-27, Ameerpet, Hyderabad, 500 016, Andhra Pradesh, India.

7. Plaintiffs are informed and believe, and thereupon allege, that Defendant Dr. Reddy's Laboratories, Inc. ("DRLI"), is a New Jersey corporation with its principal place of business at 200 Somerset Corporate Boulevard (Bldg II), Bridgewater, NJ 08807.

8. Plaintiffs are informed and believe, and thereupon allege, that DRLI is a wholly owned subsidiary of DRLL.

9. Plaintiffs are informed and believe, and thereupon allege, that DRLI develops, manufactures, distributes, sells, and markets generic products for sale and use throughout the United States, including within this judicial district.

10. Plaintiffs are informed and believe, and thereupon allege, that DRLL operates in the United States through its wholly owned subsidiary and agent, DRLI.

11. Plaintiffs are informed and believe, and thereupon allege, that DRLI is controlled and/or dominated by DRLL.

12. Plaintiffs are informed and believe, and thereupon allege, that DRLL and DRLI have common officers and directors, and DRLL and DRLI have represented to the public that they are a unitary entity.

13. Plaintiffs are informed and believe, and thereupon allege, that, the acts of DRLI complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of DRLL.

II.

NATURE OF THE ACTION

14. This is an action for patent infringement. This action relates to an Abbreviated New Drug Application ("ANDA") filed by Dr. Reddy's Laboratories with the United States

Food and Drug Administration ('FDA") for approval to market generic versions of Plaintiffs' DEXILANT products.

15. Plaintiffs are informed and believe, and thereupon allege, that Dr. Reddy's Laboratories has been infringing, is infringing, or will infringe one or more claims of each of the Asserted Patents.

III.

JURISDICTION AND VENUE

16. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including 35 U.S.C. § 271. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

17. Plaintiffs are informed and believe, and thereupon allege, that Dr. Reddy's Laboratories is in the business of developing, formulating, manufacturing, marketing, offering to sell, selling, and commercializing pharmaceutical products. DRLL and DRLI maintain a website at *http://www.drreddys.com* (the "Dr. Reddy's Website"). According to that website, Dr. Reddy's Laboratories is "an emerging global pharmaceutical company," which produces "branded and unbranded generics." The Dr. Reddy's Website further states that Dr. Reddy's Laboratories' "products are marketed globally, with a focus on India, US, Europe, and Russia."

18. Plaintiffs are informed and believe, and thereupon allege, that DRLL, either directly or through one or more of its wholly owned subsidiaries and/or agents develops, manufactures, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

19. Plaintiffs are informed and believe, and thereupon allege, that DRLI, with the assistance and/or at the direction of DRLL, develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

20. Plaintiffs are informed and believe, and thereupon allege, that DRLL and DRLI have generated significant revenue from purchases made by Dr. Reddy's Laboratories'

prescription drug product customers, who are located throughout the United States, including within this judicial district.

21. Plaintiffs are informed and believe, and thereupon allege, that DRLL and DRLI operate as an integrated, unitary business.

22. Plaintiffs are informed and believe, and thereupon allege, that DRLL and DRLI acted in concert to develop generic copies of Plaintiffs' DEXILANT capsules, and to seek approval from the FDA to sell generic copies of Plaintiff's DEXILANT capsules throughout the United States and in this judicial district.

23. This Court has personal jurisdiction over Dr. Reddy's Laboratories because Dr. Reddy's Laboratories has purposefully availed itself of the privilege of doing business in the State of New York by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including the State of New York, and/or by selling, directly or through its agents, pharmaceutical products in the State of New York.

24. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), 1391(c), 1391(d) and/or 1400(b).

IV.

FACTUAL BACKGROUND

A. Asserted Patents

1. The '276 Patent

25. On December 16, 2003, U.S. Patent No. 6,664,276, titled "Benzimidazole Compound Crystal," was duly and legally issued to Takeda Chemical Industries, Ltd., as assignee of named inventors Akira Fujishima, Isao Aoki, and Keiji Kamiyama. On June 29, 2004, Takeda Chemical Industries, Ltd., changed its name to Takeda Pharmaceutical Company Limited (i.e., TPC). The change of the name of the assignee of the '276 Patent to TPC was recorded in the PTO on January 19, 2005. A true and correct copy of the '276 Patent is attached as Exhibit A to this Complaint.

26. The expiration date of the '276 Patent listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (published by the FDA and commonly known as the Orange Book) is June 15, 2020.

2. The '755 Patent

27. On September 7, 2010, U.S. Patent No. 7,790,755, titled "Controlled Release Preparation," was duly and legally issued to TPC, as assignee of named inventors Yohko Akiyama, Takashi Kurasawa, Hiroto Bando, and Naoki Nagahara. A true and correct copy of the '755 Patent is attached as Exhibit B to this Complaint.

28. The expiration date of the '755 Patent listed in the Orange Book is August 2, 2026.

B. DEXILANT

29. Plaintiff TPNA is the registered holder of approved New Drug Application No. 22-287 for the manufacture and sale of the drug dexlansoprazole, a proton pump inhibitor, for the treatment of all grades of erosive esophagitis, maintaining healing of esophagitis, and treating heartburn associated with symptomatic non-erosive gastroesophageal reflux disease ("GERD"). Plaintiff TPA sells dexlansoprazole in the United States under the trade name DEXILANT, in 30 mg and 60 mg dosage forms. The 30 mg and 60 mg dosage forms of DEXILANT were approved by the FDA on January 30, 2009.[1]

30. Plaintiffs are informed and believe, and thereupon allege, that DEXILANT is the first and only acid reflux disease treatment specifically designed for the release of medicine in two stages over time. The key to the two stage release is DEXILANT's Dual Delayed Release™ formulation ("DDR"). DDR combines two different types of granules in one pill.

[1] Plaintiffs originally marketed the drug dexlansoprazole under the proprietary name KAPIDEX. On March 4, 2010, the FDA announced that TPNA would start marketing KAPIDEX under the new name DEXILANT to avoid potential confusion with two other medications, CASODEX and KADIAN.

DEXILANT releases one dose of medicine within an hour of taking a pill. Then, around four to five hours later, DEXILANT releases a second dose of medicine.

31. The Asserted Patents are listed in the Orange Book in support of Plaintiffs' DEXILANT (dexlansoprazole) delayed release capsules, in 30 mg and 60 mg dosage forms.

C. Infringement by DRLL

32. On information and belief, Dr. Reddy's Laboratories has submitted ANDA No. 202-193 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The ANDA seeks approval to market dexlansoprazole delayed release capsules in 30 mg and 60 mg dosage forms (the "Proposed Capsules") as a generic version of DEXILANT, prior to the expiration dates of the Asserted Patents.

33. On February 21, 2011, TPC received a letter dated February 18, 2011 (the "Notice Letter") from Dr. Reddy's Laboratories addressed to TPC and TPNA. This was the first Notice Letter that any of the Plaintiffs received related to ANDA No. 202-193.

34. The Notice Letter stated that the ANDA includes a Paragraph IV Certification that, in Dr. Reddy's Laboratories' opinion, the '276 Patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer to sell, or importation into the U.S. of the Proposed Capsules.

35. The Notice Letter did not provide any certification with regard to the '755 Patent, even though that patent was listed in the Orange Book in support of DEXILANT (dexlansoprazole) delayed release capsules, in both 30 mg and 60 mg forms, before the date of the Notice Letter.

36. Plaintiffs are informed and believe, and thereupon allege, that the ANDA does not provide any valid basis for concluding that that the '276 Patent and the '755 Patent are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the Proposed Capsules.

37. The Notice Letter also stated that the ANDA included a Paragraph III Certification, pursuant to which Dr. Reddy's Laboratories seeks approval of its ANDA after

U.S. Patent Nos. 6,462,058 (the "'058 Patent") , 6,939,971 (the "'971 Patent"), and 7,285,668 (the "'668 Patent") expire "or are found to be invalid, unenforceable or not infringed by an equivalent product."

38. Because the quoted language from the Notice Letter is not part of the language for a Paragraph III Certification authorized by 21 U.S.C. § 355(j)(2)(A)(vii)(III) and 21 C.F.R. § 314.94(a)(12)(i)(A)(3), counsel for Plaintiffs wrote to counsel for Dr. Reddy's Laboratories on March 24, 2011, to request confirmation that the ANDA includes Paragraph III Certifications for the '058, '971, and '668 Patents and that Dr. Reddy's Laboratories will provide Plaintiffs with notice if and when Dr. Reddy's Laboratories amends its certification for any one of these patents to a Paragraph IV Certification. Counsel for Dr. Reddy's Laboratories provided the requested confirmation by voicemail on March 25, 2011.

39. Plaintiffs are informed and believe, and thereupon allege, that the submission of the ANDA to the FDA constitutes infringement of the Asserted Patents under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, offer to sell, sale, or import of the Proposed Capsules would infringe the Asserted Patents under 35 U.S.C. § 271(a)–(c).

40. Plaintiffs commenced this action within 45 days of receiving the Notice Letter, as required by 21 U.S.C. § 355(j)(5)(B)(iii).

V.

CLAIMS FOR RELIEF

COUNT I

(Patent Infringement of U.S. Patent No. 6,664,276)

41. Plaintiffs incorporate by reference and reallege paragraphs 1 through 40 above as though fully restated herein.

42. Pursuant to 35 U.S.C. § 271(e)(2), Dr. Reddy's Laboratories' submission of ANDA No. 202-193 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the Proposed Capsules was an act of infringement of the '276 Patent.

43. Unless Dr. Reddy's Laboratories is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Dr. Reddy's Laboratories' infringement of the '276 Patent. Plaintiffs do not have an adequate remedy at law.

COUNT II

(Patent Infringement of U.S. Patent No. 7,790,755)

44. Plaintiffs incorporate by reference and reallege paragraphs 1 through 43 above as though fully restated herein.

45. Pursuant to 35 U.S.C. § 271(e)(2), Dr. Reddy's Laboratories' submission of ANDA No. 202-193 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the Proposed Capsules was an act of infringement of the '755 Patent.

46. Unless Dr. Reddy's Laboratories is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Dr. Reddy's Laboratories' infringement of the '755 Patent. Plaintiffs do not have an adequate remedy at law.

VI.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. For a determination that Dr. Reddy's Laboratories has infringed each of the Asserted Patents;

B. For a determination that the commercial use, sale, offer for sale, manufacture, and/or importation by Dr. Reddy's Laboratories of the Proposed Capsules would infringe each of the Asserted Patents;

C. For a determination, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date for approval of ANDA No. 202-193 be no earlier than the expiration date of the last of the Asserted Patents, including any extensions or adjustments;

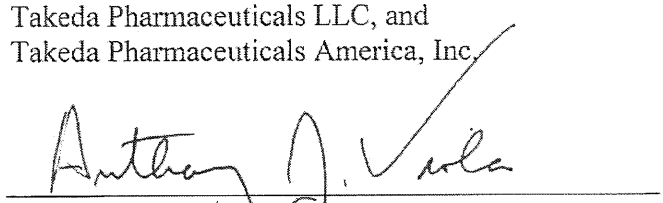
D. For an order preliminarily and permanently enjoining Dr. Reddy's Laboratories and its affiliates, subsidiaries, officers, directors, employees, agents, representatives, licensees, successors, assigns, and all those acting for them and on their behalf, or acting in concert with them directly or indirectly, from infringing the Asserted Patents; and

E. For such other and further relief as this Court deems just and proper.

Respectfully Submitted,

DATED: New York, New York
April 1, 2011

Takeda Pharmaceutical Co., Ltd.,
Takeda Pharmaceuticals North America, Inc.,
Takeda Pharmaceuticals LLC, and
Takeda Pharmaceuticals America, Inc.



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